UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA and the STATES of COLORADO, CONNECTICUT, THE DISTRICT OF COLUMBIA, FLORIDA, ILLINOIS, INDIANA, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, OHIO, OKLAHOMA, TEXAS, AND VIRGINIA *ex rel.* BNHT LLC,

Plaintiffs,

v.

LIFE SPINE INC., MICHAEL BUTLER, and JOSEPH LOY,

Defendants.

UNITED STATES OF AMERICA,

Plaintiff-Intervenor

v.

LIFE SPINE, INC., MICHAEL BUTLER, and RICHARD GREIBER,

Defendants.

1311

18 Civ. ~~1131~~ (JSR)

UNSEALING ORDER

WHEREAS, the United States of America (the "Government") has intervened in the above-referenced *qui tam* action pursuant to the False Claims Act, 31 U.S.C. §§ 3730(b)(2) and (4), and has asserted claims against defendants Life Spine, Inc., Michael Butler, and Richard Greiber;

IT IS HEREBY ORDERED that:

1. The seal shall be lifted as to this Order and any matter occurring in this action on or subsequent to the date of this Order.

2. The Complaint of Relator BNHT, LLC, filed on or about February 14, 2018, and the United States' Notice of Election to Intervene, filed on or about April 22, 2019, shall be unsealed.

3. All other previously filed documents in this action shall remain under seal and shall not be made public.

Dated: New York, New York
July 23, 2019

HON. JED S. RAKOFF
United States District Judge

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COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA

JURY TRIAL DEMANDED

UNITED STATES OF AMERICA,

Plaintiff-Intervenor

v.

LIFE SPINE, INC., MICHAEL BUTLER, and RICHARD GREIBER,

Defendants.

Plaintiff the United States of America (the "United States" or the "Government"), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York, alleges for its Complaint-In-Intervention as follows:

PRELIMINARY STATEMENT

1. The Government brings this Complaint-In-Intervention seeking damages and penalties against Life Spine, Inc. ("Life Spine"), Michael Butler ("Butler"), and Richard Greiber ("Greiber") (collectively "Defendants") under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), and, in the alternative, under the common law for unjust enrichment. From January 2012 through at least December 2018 (the "Relevant Period"), Life Spine, with the knowledge, involvement, and participation of Butler and Greiber, offered and paid remuneration, in the form of millions of dollars in consulting fees, royalties, and intellectual property acquisition fees, to surgeons to induce them to use Life Spine's spinal implants, devices, and equipment ("Life Spine Products"), in violation of the Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b(b), and thereby caused false claims for payment to be submitted to and paid by Medicare and Medicaid.

2. Defendants aggressively recruited surgeons who had the potential to use a high volume of Life Spine Products to enter into agreements to serve as paid "consultants" and/or to transfer their patents/patent applications to Life Spine in exchange for payments and promised support to bring the surgeons' new products to market. Defendants tied these agreements and the associated payments — as well as the company's continued commitment to devote resources to the surgeons' product development projects — to the surgeons' usage of Life Spine Products. Defendants expected surgeons to commit to using Life Spine Products at a certain level in exchange for the consulting fees, royalties, and intellectual property acquisition fees paid to

them. (Surgeons who received these payments during the Relevant Period are hereafter referred to as "Paid Surgeons.")

3. Defendants closely tracked Paid Surgeons' usage of Life Spine Products to ensure that the payments to them were generating sufficient sales revenues for the company. Life Spine went so far as to generate a report that compared surgeon consulting, royalty, and intellectual property payments to surgeon product usage levels, and then calculated an "ROI" (return on investment) for each surgeon based on those figures. If a Paid Surgeon's usage was too low, Defendants pressured the surgeon to use more Life Spine Products during his or her surgeries, often reminding the surgeon that the company expected a certain level of usage in exchange for its payments.

4. The kickback scheme was lucrative. Paid Surgeons accounted for approximately half of Life Spine's total domestic sales of spinal products during the Relevant Period. These surgeons used Life Spine Products during procedures performed on Medicare and Medicaid patients, which resulted in the submission of kickback-tainted false claims to Medicare and Medicaid.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the claims brought under the FCA pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the common law claim for unjust enrichment pursuant to 28 U.S.C. § 1345.

6. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process.

7. Venue lies in this District pursuant to 31 U.S.C. § 3732(a), because Life Spine does business in this District. Specifically, Life Spine markets and sells Life Spine Products to health care providers located in this District.

PARTIES

8. Plaintiff is the United States of America suing on its own behalf and on behalf of the United States Department of Health and Human Services ("HHS"), and its component agency, the Centers for Medicare and Medicaid Services ("CMS"), which administers the Medicare program and is responsible for overseeing the Medicaid program.

9. Relator BNHT, LLC ("Relator") is a Delaware limited liability company, whose members are four former Life Spine employees. In February 2018, Relator filed an action pursuant to the FCA and analogous state laws alleging that Life Spine and Butler engaged in an illegal kickback scheme by paying physicians ostensibly for consulting services when in reality the payments were intended to induce sales of Life Spine Products. No official of the United States charged with responsibility to act in the circumstances knew or should have known of the facts material to the FCA claims related to the kickbacks alleged herein prior to February 2018.

10. Defendant Life Spine is a Delaware corporation with its principal place of business in Huntley, Illinois. Life Spine designs, develops, manufactures, and markets medical devices and equipment, including implants and instruments, primarily used in spine surgeries performed by orthopedic surgeons and neurosurgeons. Life Spine does business throughout the United States, including in the Southern District of New York.

11. Defendant Michael Butler is the founder, President, and Chief Executive Officer of Life Spine and is its majority shareholder. During the Relevant Period, Butler was closely involved in overseeing the operations of Life Spine. Butler also owns 100% of Gizmo Medical

Ltd. and Gizmo Medical LLC, entities through which Life Spine purchases instruments from Zibo Dante Economic and Trade Co. Ltd., a Chinese manufacturing entity that is 80% owned by Gizmo Medical LLC. Based on his ownership interest, Butler receives commissions from Gizmo Medical Ltd. on Life Spine's purchases of instruments from this entity. Butler resides in Illinois.

12. Defendant Richard Greiber is Life Spine's Vice President of Business Development. Greiber has worked for Life Spine since November 2006 and has held various management positions. From 2009 to 2015, Greiber served as Vice President of Business Development and Professional Relations. While in this position, Greiber oversaw Life Spine's marketing department, and was involved in selecting and approving surgeons who served as paid consultants for Life Spine and negotiating and reviewing the terms of agreements with surgeons. Greiber was also supposed to be responsible for ensuring that Life Spine's relationships with surgeons complied with applicable laws and regulations, including the AKS. Greiber resides in Illinois.

BACKGROUND

I. The Anti-Kickback Statute and the False Claims Act

13. The FCA establishes liability to the United States for an individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B). "Knowingly" is defined to include actual knowledge, reckless disregard and deliberate indifference. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

14. The AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to

induce such person . . . to purchase, . . . order, or arrange for or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Payments by a medical device company to doctors to induce them to choose to use the company's products in surgeries or other medical procedures that are ultimately paid for by federal health care programs are examples of such illegal remuneration. Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2), (6).

15. The AKS arose out of congressional concern that remuneration given to those who can influence health care decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the Medicare and Medicaid programs, as well as other federal health care programs, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

16. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]."

17. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the [FCA], even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

18. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under Medicare and Medicaid.

19. By offering to provide and providing kickbacks to doctors to induce them to use Life Spine Products, Defendants have caused false claims to be submitted to Medicare and Medicaid.

20. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), the FCA civil penalties are $5,500 to $11,000 for violations occurring on or after September 29, 1999, but before November 2, 2015, *see* 64 Fed. Reg. 47099, 47103 (1999), and $11,181 to $22,363 for violations occurring on or after November 2, 2015, *see* 83 Fed. Reg. 3944, 3945 (2018).

II. Medicare

21. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare Program, to pay for the costs of certain health care services. 42 U.S.C. §§ 1395 *et seq.* Entitlement to Medicare benefits is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1.

22. HHS is responsible for the administration and supervision of the Medicare Program. CMS is an agency of HHS and is directly responsible for the administration of the Medicare program. For purposes of this action, there are two primary components to the Medicare Program: Part A and Part B. Medicare Part A authorizes payment for institutional care, including inpatient hospital services, skilled nursing facilities, and home health care. *See*

42 U.S.C. §§ 1395c to 1395i-5. Medicare Part B is a federally subsidized, voluntary insurance program that covers a percentage of the fee schedule for physician services as well as a variety of "medical and other services." *See* 42 U.S.C. §§ 1395j to 1395w-6.

23. To participate in the Medicare Program, a health care provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the Medicare Program and in order to receive reimbursement from Medicare. The provider agreement specifically requires compliance with the AKS.

A. Medicare Part A

24. Part A of the Medicare Program authorizes payment for institutional care, including hospitalization, for eligible patients. Under Medicare Part A, hospitals enter into an agreement with Medicare to provide health care items and services to treat Medicare patients. The hospital, also called a "provider," is authorized to bill Medicare for that treatment.

25. During the Relevant Period, CMS reimbursed hospitals for inpatient Part A services through Medicare Administrative Contractors ("MACs").

26. MACs are private insurance companies that are responsible for determining the amount of payments to be made to providers. *See* 71 Fed. Reg. 67960, 68181 (Nov. 24, 2006). Under their contracts with CMS, MACs review, approve, and pay Medicare bills, called "claims," received from hospitals. *See* 42 C.F.R. § 421.5(b). Those claims are paid with federal funds.

27. Since 2007, in order to get paid, a hospital must complete and submit a claim for payment on a CMS 1450 form (also known as UB-04). This form contains patient-specific information including the diagnosis and types of services that are assigned or provided to the

Medicare patient. The Medicare Program relies upon the accuracy and truthfulness of the CMS 1450 forms to determine whether the service is payable and what amounts the hospital is owed.

28. In addition, and at the end of each fiscal year, a hospital submits to the MAC a form referred to as a "cost report," which may identify any outstanding costs that the hospital is claiming for reimbursement for that year. By auditing and reviewing cost reports, the Medicare Program ensures the accuracy of previously submitted claims and can make adjustments where there is a discrepancy between the hospital's costs and Medicare reimbursements. The Medicare Program relies upon the accuracy and truthfulness of the cost report to determine what amounts, if any, the hospital is owed, or what amounts the hospital has been overpaid during the year.

29. In 1983, Congress established the prospective payment system ("PPS") as the system by which hospitals are reimbursed for inpatient hospital costs. Under PPS, the amount Medicare pays a hospital for treating an inpatient Medicare beneficiary is based on a variety of factors, including the particular condition that led to the patient's admission to, or that was principally treated by, the hospital.

30. Under PPS, a patient's illness or condition is categorized under a classification system called a diagnostic related group ("DRG"). The DRG is one of the factors used to determine how much the hospital will be paid under Medicare and reflects the resources the patient's condition or treatment typically requires. The MAC uses the patient specific information (for example, the diagnosis codes) submitted by the hospital on the CMS Form 1450 to determine what DRG is assigned to a certain claim, and hence, what amount will be paid.

31. Medicare utilizes the DRG information to determine the level of reimbursement the hospital receives for the expected costs related to a beneficiary's hospitalization, including the cost of medical and surgical equipment utilized to care for the patient. The Part A claims

submitted by a hospital with an associated beneficiary DRG are intended to compensate the hospital for the costs of any spinal implants or other devices, where those devices are appropriately used to treat a Medicare beneficiary.

B. Medicare Part B

32. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and by contributions from the Federal Treasury. Eligible individuals who are 65 or older, or disabled, may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums. In addition to enrollment agreements, the vast majority of health care providers elect to enter into Medicare participation agreements, which allow the beneficiaries' claims to be assigned directly to the provider. Pursuant to Medicare Participation Agreements, payments under Medicare Part B are typically made directly to service providers and practitioners, such as physicians, rather than to the patient/beneficiary In that case, the physician bills the Medicare Program directly.

33. The United States provides reimbursement for Medicare Part B claims from the Medicare Trust Fund through CMS. MACs are responsible for processing the payment of Medicare Part B claims to providers on behalf of CMS.

34. In order to bill Medicare, a physician must submit an electronic or hard-copy claim form called a CMS 1500 form to the carrier. When the claim is submitted, the physician certifies that he or she is knowledgeable of Medicare's requirements and that the claim complies with applicable laws and regulations, including the AKS.

35. Physicians wishing to submit the CMS 1500 form electronically must submit a provider enrollment form.

36. For a claim to be paid by the Medicare Part B Program, the claim must identify each service rendered to the patient by the physician. The service is identified through a

corresponding code that is listed in the American Medical Association publication called the Current Procedural Terminology ("CPT") Manual. The CPT Manual is a systematic list of codes for procedures and services performed by or at the direction of a physician. Each procedure or service is identified by a five-digit CPT code.

III. Medicaid

37. The Medicaid Program was also created in 1965 as part of the Social Security Act, which authorized federal grants to states for medical assistance to low-income, blind, or disabled persons, or to members of families with dependent children or qualified pregnant women or children. The Medicaid Program is jointly financed by the federal and state governments. CMS administers Medicaid on the federal level. Within broad federal rules, each state determines eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. The states directly pay providers, with the states obtaining the federal share of the payment from accounts that draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994).

38. The majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the

quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). *See* 42 C.F.R. § 430.30.

39. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes.

40. Providers who participate in the Medicaid program must sign enrollment or other participation agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

41. Furthermore, in many states, Medicaid providers must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

IV. Reimbursement for Spine Surgeries Using Medical Devices

42. As discussed above, costs associated with spine surgeries utilizing medical devices are separately billed by the hospitals and surgeons to payors, including Medicare and Medicaid.

43. Hospitals submit claims to Medicare and Medicaid for the inpatient costs associated with the surgeries, including the cost of the medical devices, on CMS 1450 claim forms. Hospital claims identify the DRG associated with the surgery, which CMS uses to determine the payment amount to the hospital, and include payment for the medical devices used during the surgery.

44. DRG codes are calculated in a manner intended to fairly compensate the hospital for all the costs associated with the surgery, including the medical device costs. DRG rates are recalculated annually based on, among other things, actual claims data.

45. For spinal implant surgeries, the hospital typically treats the spinal implants as a "physician preference" item, meaning surgeons select the type of spinal implant to be purchased and used for their surgeries. However, the devices utilized in a spinal surgery are generally purchased by the hospital from the manufacturer.

46. The surgeon performing the surgical procedure separately bills Medicare Part B or Medicaid for his or her professional services on a CMS 1500 form, identifying the surgical procedure by the appropriate CPT code.

FACTUAL ALLEGATIONS

I. Life Spine's Business

47. Life Spine is a privately held company that was founded in 2004 and has approximately 80 employees. Life Spine develops, markets, and sells medical devices and equipment that are primarily used in spinal surgeries performed by orthopedic surgeons and neurosurgeons. Life Spine also has a smaller division focused on devices and equipment used in foot and ankle surgeries. Life Spine sells its products primarily in the United States but also has some international business.

48. Life Spine has a portfolio of more than 100 patents. It markets a wide range of spinal implant products but with a specialization in micro-invasive expandable interbody fusion implants.

49. Life Spine enters into agreements with distributors who promote the sale and use of the company's products to surgeons within their designated territories. The majority of Life Spine Products are sold through distributors. Distributors receive a commission from Life Spine

for every sale of a Life Spine Product that is used by a surgeon represented by that distributor. Life Spine paid its distributors reduced commissions for products used by surgeons who served as paid consultants, and who Life Spine therefore expected would use its products regardless due to the payments the company made to those surgeons.

50. Because surgeons typically select the implantable device they use during surgical procedures, Life Spine focused much of its sales and marketing efforts on persuading surgeons, its ultimate customers, to select its products over competitor products.

II. Life Spine Made Payments to Surgeons Who Were Potential High-Volume Users of Life Spine Products.

51. Life Spine's business model focused on offering surgeons lucrative agreements to induce them to use Life Spine Products when performing spinal procedures. Life Spine, at the direction of Butler, sought to enter into agreements with surgeons who had the potential to use a high volume of Life Spine Products in their practices and thus were particularly valuable sales targets. Life Spine entered into written agreements with surgeons, but those agreements did not disclose the collateral understandings that Life Spine had with those surgeons as to their expected usage of Life Spine Products.

52. Life Spine senior executives, including Butler and Greiber, were responsible for recruiting surgeons and negotiating the terms of their agreements with them and/or their representatives. They often did so by inviting the surgeons to visit Life Spine's headquarters for a training or meeting (either directly or through Life Spine's sales or marketing staff), or by taking the surgeons out to dinners, after which they would discuss the terms of potential agreements in private meetings. Greiber personally negotiated and signed many of the agreements when he served as Vice President of Business Development and Professional Relations.

53. During the Relevant Period, Life Spine, with the knowledge, involvement, and participation of Butler and Greiber, entered into agreements with dozens of surgeons pursuant to which surgeons received compensation from Life Spine. These agreements included medical education agreements, product development agreements, and intellectual property purchase or licensing agreements. A particular agreement could cover more than one type of arrangement and individual surgeons frequently entered into more than one type of agreement. As described further below, Defendants used these agreements as a vehicle to pay surgeons illegal kickbacks in the form of consulting fees, royalties, and intellectual property acquisition payments, in order to induce surgeons' usage of Life Spine Products.

54. During the Relevant Period, Life Spine, with the knowledge, involvement, and participation of Butler, paid more than $7 million in consulting fees, royalties, and intellectual property acquisition payments to surgeons. Life Spine did not report all of these payments to CMS as required under the Physician Payment Sunshine Act, Section 6002 of the PPACA. Further, for a portion of the Relevant Period, Life Spine also compensated surgeons in the form of warrants in the company.

A. Medical Education Agreements ("Med Ed Agreements")

55. Life Spine entered into consulting agreements under which surgeons were paid an hourly rate (typically $500 per hour) to provide training and/or educational services. These services included, among other things, speaking about Life Spine Products, preparing research papers related to Life Spine Products, presenting at trade shows or conferences, participating in clinical studies of Life Spine Products, and training Life Spine's own staff. These agreements were called "medical education" agreements.

56. For example, Life Spine conducted training events at its headquarters in Huntley, Illinois, for physicians and others as a way to market Life Spine Products. Life Spine paid surgeons to attend these events, demonstrate procedures at cadaver labs, and make presentations.

57. In addition, Life Spine paid surgeons to conduct clinical studies on Life Spine Products or to provide post-market feedback regarding their use of Life Spine Products with their patients. Life Spine also paid surgeons for simply allowing Life Spine employees to observe surgeons perform procedures.

B. Product Development Agreements ("PD Agreements")

58. Life Spine also retained surgeons as consultants to advise on specific new products that were in the development stage. In addition to paying surgeons an hourly rate (typically $500 per hour) for time purportedly spent providing input on Life Spine Products, Life Spine also paid surgeons royalties on future sales of the product in the event that it went to market.

59. Life Spine contracted with up to eight surgeons for each new product development project and launched an estimated 15-30 projects per year. Life Spine frequently retained the same surgeon to consult on several different products at the same time.

C. Intellectual Property Agreements ("IP Agreements")

60. Life Spine also entered into agreements to purchase (or sometimes license) surgeons' patents or patent applications. Life Spine frequently paid surgeons initial, up-front acquisition fees, which in some cases were hundreds of thousands of dollars. In addition, surgeons received royalties on the sales of any products developed based on the patents, which typically were 5-7% of net sales.

61. Butler reviewed the patents that Life Spine considered purchasing from surgeons and was involved in the negotiation of the terms of the IP Agreements, including the initial acquisition fees and any royalties.

62. Pursuant to IP Agreements, Life Spine also committed to using its resources to assist with the development, marketing, sale, and distribution of products based on the patents. These projects were sometimes internally referred to as "vanity projects" because they were designed not to necessarily launch a promising new spinal product, but instead primarily to foster a closer relationship between the company and the surgeons by appealing to the vanity of the surgeons. Life Spine, at the direction of Butler, took on these projects at least in part to induce surgeons to use Life Spine Products.

III. Approximately Half of Life Spine's Sales of Spinal Products Were in Connection with Paid Surgeons' Spinal Surgeries.

63. While Life Spine's Paid Surgeons constituted only a small fraction of the company's total surgeon customers, roughly half of Life Spine's total domestic sales of spinal products during the Relevant Period were attributable to surgeries performed by Paid Surgeons.

64. Many of the Paid Surgeons were high-volume users of Life Spine Products. Indeed, approximately 21 of the top 30 Life Spine surgeon customers during the Relevant Period received consulting fees, royalties, and/or intellectual property acquisition payments from Life Spine.

65. Most of the Paid Surgeons substantially increased their usage of Life Spine products after entering into agreements with Life Spine. Total revenues from the sale of Life Spine Products increased substantially while the kickback scheme was in place. Annual revenues jumped by more than 80% from 2013 to 2018.

66. The proportion of Life Spine's sales attributable to Paid Surgeons was considered a red flag by several outsiders. For example, in September 2014, the principal of another spinal company considered entering into a merger or acquisition deal with Life Spine, but pulled out after his company's due diligence discovered that "14 of [Life Spine's] top 20 surgeons [were] receiving remuneration or are shareholders." The individual also expressed concern that "[e]xcessive physician remuneration brings into question the ability of Life Spine . . . to build revenues and value through arms-length transactions."

67. Similarly, in September 2016, potential investors in Life Spine listed "[i]ncentives to docs (royalties, consulting agreements, etc.)" as one of several "[k]ey topics of discussion" for a meeting with Butler and other Life Spine senior management.

IV. Life Spine Paid Surgeons to Induce Them to Use Life Spine Products.

68. Life Spine, with the knowledge, involvement, and participation of Butler and Greiber, utilized Med Ed Agreements, PD Agreements, and IP Agreements as vehicles to funnel payments to surgeons in order to induce them to use, or increase their usage of, Life Spine Products. Life Spine executives, including Butler and Greiber, tied these agreements and the resulting payments — as well as the company's continued commitment to devote resources to the surgeon's product development projects under IP Agreements — to the surgeon's usage of Life Spine Products.

69. Life Spine managers frequently advised surgeons that they were expected to commit to using a certain volume of Life Spine Products in order to serve, or continue to serve, as consultants.

70. For example, in February 2017, a Texas-based distributor who represented a surgeon who had recently become a Life Spine consultant sent a senior Life Spine executive a letter pushing back after that executive tied the surgeon's consultancy to his product usage. The

letter stated, "you clearly stepped over the line after you told me that [the doctor] needed to do more volume for the company because Life Spine was engaging him."

71. In an August 2018 text message exchange, two members of Life Spine's sales staff discussed how a surgeon's usage of Life Spine Products could translate into a consulting opportunity: "Even at 50k per month [in sales], I can make the argument for him to be on a project."

72. The company utilized potential paid consulting opportunities as a tool to attract new business from surgeons. For example, in July 2018, one of Life Spine's marketing managers texted a Life Spine sales representative: "I also have a silver bullet for you. We are getting in parallel and 15 degree post pack ProLifts. I need a few (possibly new) surgeons to evaluate with our delivery system . . . . We will sign them up in a Med ed agreement and compensate them for the input forms." The sales representative responded: "As for the post pack Silver Bullet, that is fabulous news. I have to be very selective and set the expectations very clearly w[ith] both distributors and surgeons. That is a nice weapon to have. Thank you sir!"

73. Surgeons frequently only started to use Life Spine Products after entering into agreements with the company. For instance, in or about August 2016, Life Spine entered into an IP Agreement under which the company purchased two patent applications from a Rhode Island-based surgeon who had not previously used Life Spine Products. Greiber initially offered to pay a $125,000 acquisition fee for the two patent applications, in addition to offering a 5% sales royalty. In response to this proposal, the surgeon's distributor sent Greiber an email asking for $200,000 and stating: "I think the offer is great especially since there hasnt [sic] been any business as of yet. On that note I expect to start doing cases the first week in August . . . ." Life Spine and Greiber quickly acceded to this request and paid the surgeon $200,000 for the two

patent applications. The surgeon began using Life Spine Products in August 2016, and ultimately was responsible for more than $2.2 million in Life Spine sales revenues.

74. Butler informed his staff that he expected Paid Surgeons to commit to using Life Spine Products. For example, in a February 2013 email to a Life Spine sales supervisor with the subject heading "Sales Process," Butler relayed his "10 commandments of sales," which included the following items:

- "Move to exclusivity with a lockout time (if we invest in Dr. Famous, they (distributor/doctor should commit as well)."
- "ROI – Everything we do has to have a tangible ROI (none of this flowery stuff where we pay for everything and get no case)"

75. In addition to paying consulting fees, royalties, and intellectual property acquisition fees, Life Spine also offered Paid Surgeons other perks to ensure their continued use of Life Spine Products. For instance, on one occasion, Life Spine took several Paid Surgeons to a Chicago Cubs game, rented two suites at the stadium, and provided the physicians with complimentary custom Cubs jerseys and gift baskets. Life Spine executives also frequently took surgeons out to dinner at high-end restaurants.

76. Butler made sure that surgeons were treated well and rewarded for their business. For instance, in an early 2018 internal text exchange discussing a Florida-based Paid Surgeon's recent sales volume and getting his "Pro-Link business," Butler asked a Life Spine manager whether the surgeon was transported "on the chopper" because he "wanted to show the guy some swag." The Life Spine employee agreed and responded that the physician "does need to get some LS attention." Life Spine also made significant annual contributions to a charity at the request of the same Paid Surgeon. When completing the form seeking approval for one of these donations, Life Spine indicated that the "business impact" for the expense was "revenue

preservation." This Florida-based Paid Surgeon received over $300,000 in payments from Life Spine and generated over $2.9 million in sales of Life Spine Products during the Relevant Period.

V. Defendants Closely Tracked Paid Surgeons' Usage of Life Spine Products to Ensure that Life Spine's Payments Were Resulting in Sales.

77. Life Spine executives and managers, including Butler and Greiber, closely tracked Paid Surgeons' usage of Life Spine Products to make sure the surgeons were holding up their end of the *quid pro quo* agreements and to know when to pressure them for more sales.

78. For years, Life Spine's finance department created and circulated to certain senior Life Spine executives, including Butler and Greiber, spreadsheets that tracked the monthly usage (*i.e.*, sales revenue figures) of Paid Surgeons and compared that usage to the consulting fees, royalties, and IP-related payments made to these surgeons during the same time period. In at least one version of the spreadsheet, Life Spine even calculated the "ROI," or return on investment, on Life Spine's payments to each of these surgeons and sorted the list of surgeons from highest to lowest ROI. Life Spine calculated the ROI figure by dividing the sales revenue associated with each surgeon's usage of Life Spine Products by the total amount paid to that surgeon in consulting fees and royalties during the period.

79. When he served as Vice President of Business Development and Professional Relations, Greiber was responsible for tracking which surgeons were paid to consult on various product development projects. In October 2015, he organized a meeting of Life Spine senior executives, including Butler, to discuss "[s]urgeon consultants and pending agreements." In advance of the meeting, Greiber circulated to Butler and the others a report that he had prepared setting forth the names of Paid Surgeons, the royalty and consulting payments each surgeon had received in 2015, and the total revenue generated from each surgeon's use of Life Spine

Products. This allowed them to easily evaluate whether the surgeon payments were resulting in business for Life Spine.

80. Life Spine management requested that sales data for Paid Surgeons be reported and tracked separately from the other sales data so that they could focus specifically on usage trends for this subclass of surgeons. For example, "Executive Corporate Dashboard" emails were circulated daily to Butler and other Life Spine executives. These "dashboards" grouped and tracked recent sales data for consulting surgeons and surgeons who had sold intellectual property to Life Spine separately from the sales data for other surgeon customers.

81. Similarly, an internal presentation setting forth the sales and marketing strategy for 2018 compared the usage of Life Spine Products by "Royalty Bearing Surgeons" in 2016 and 2017, noting a 53% year-over-year increase.

82. Life Spine executives, including Butler and Greiber, used these reports and data to determine whether Paid Surgeons were fulfilling their "commitment" to use Life Spine Products in their surgeries. When those surgeons' numbers dropped, senior managers would contact the surgeons and/or their distributors to remind them of their commitment and to pressure them to increase their use of Life Spine Products. On multiple occasions, Butler personally urged Paid Surgeons to increase their product usage.

VI. Surgeon-Specific Examples

83. As described above, Life Spine, with the knowledge, involvement, and participation of Butler and Greiber, incentivized Paid Surgeons to use high volumes of Life Spine Products by retaining them as paid consultants and purchasing and funding the development of their intellectual property. These surgeons' usage of Life Spine Products closely corresponds with when they entered their agreements with the company and the payments they received. Below are examples of surgeons who received kickbacks from Life Spine and used

Life Spine Products when performing surgeries on Medicare and Medicaid patients. Claims related to these surgeries were submitted to and paid by Medicare and Medicaid.

A. An Indiana-Based Surgeon

84. During the Relevant Period, Indiana-based Dr. A[1] was by far Life Spine's largest revenue-generating surgeon, accounting for over $22.9 million in Life Spine Product sales, including over 24% of sales in 2016 and 2017.

85. Dr. A was also Life Spine's highest paid surgeon. Dr. A entered into several agreements to provide medical education and consulting services on product development projects. Life Spine frequently invited and paid Dr. A to conduct events for Life Spine, including events at vacation destinations such as Aruba and Valencia, Spain. During the Relevant Period, Life Spine paid Dr. A over $295,000 in consulting and royalty fees.

86. Life Spine identified or created projects for Dr. A in order to pay him to continue using its products as Dr. A frequently indicated his displeasure with Life Spine or threatened to stop using Life Spine Products.

87. In addition to the consulting agreements, Life Spine and Dr. A entered into two IP Agreements. In the first, dated January 1, 2016, Life Spine purchased two patent applications from Dr. A in exchange for a $2 million acquisition fee (to be paid in installments) and a 5% royalty on future product sales. In the second, dated January 1, 2018, Life Spine purchased another patent application from Dr. A, also in exchange for $2 million (to be paid in installments) and a 5% royalty.

[1] This Complaint-In-Intervention uses pseudonyms for the names of specific Paid Surgeons. The Government will disclose the names of these surgeons to Defendants upon request.

88. Notably, Dr. A's usage of Life Spine Products skyrocketed from approximately $2.2 million in 2015 to approximately $7 million in 2016, after he entered into the first of his IP Agreements with Life Spine.

89. The second IP Agreement was executed just weeks after Dr. A advised Life Spine executives that he was angry that the company had selected another consultant (and competitor of Dr. A) to serve as a keynote speaker at an event in October 2017. Upon learning of the event, Dr. A texted Butler: "WTF is this[.] Are you serious Mike[?] this better be a joke Or we have a serious problem." Butler and Life Spine's Vice President of Marketing promptly reached out to Dr. A to mitigate the damage to their relationship. After Dr. A threatened not to use Life Spine products anymore, Life Spine entered into the second $2 million IP Agreement with him. In addition, early in March 2018, Life Spine offered Dr. A consulting engagements on additional product development projects.

90. Butler was in frequent direct contact with Dr. A during the Relevant Period and monitored his usage of Life Spine Products. They regularly communicated by text about business and personal issues. For example, in a late 2017 text exchange, Butler told Dr. A: "We are crushing '18. There is so much moving. Trying to get you some podiums." Dr. A responded: "Gotta get famous. Bitches like famous ppl." Dr. A later texted Butler a picture of the Porsche he had just purchased.

91. Dr. A also requested favors from Life Spine, and the company, including Butler, made every effort to make sure its top customer was happy. For example, in late 2017, Dr. A. asked Butler to consider hiring his cousin. Dr. A asked Butler whether that "present[ed] a problem . . . from a compliance point of view [d]ue to our relationship." A couple of weeks

later, Life Spine's Vice President of Marketing and Business Development emailed Dr. A's cousin to try to schedule an interview.

92. Dr. A used Life Spine Products when performing spinal surgeries on a significant number of Medicare patients at various hospitals, including St. Mary Medical Center – Hobart, Northwest Regional Surgery Center, and Munster Specialty Surgery Center. Medicare Part A and Medicare Part B claims relating to these surgeries were submitted and paid. Those claims were false because they were tainted by illegal kickbacks and thus were ineligible for reimbursement.

B. A Colorado-Based Surgeon

93. Another Paid Surgeon, Colorado-based Dr. B, was responsible for over $3.7 million of Life Spine's sales revenues during the Relevant Period. In terms of revenue generated, Dr. B was Life Spine's second largest surgeon customer during this period (after Dr. A).

94. In January 2012, Life Spine entered into an IP Agreement under which Life Spine licensed a patent for a compression plate owned by a company associated with Dr. B. Life Spine committed to assist with the development of the product and agreed to provide the surgeon's company royalties based on a percentage of future sales. Greiber signed the agreement on behalf of Life Spine.

95. Pursuant to other agreements between Dr. B and Life Spine, the company paid Dr. B over $125,000 in consulting and royalty fees during the Relevant Period.

96. In exchange for these payments and the promise that Life Spine would work to get FDA approval for Dr. B's plate and make it commercially available and thus a source of royalties, Dr. B used Life Spine products nearly exclusively from 2012 through 2015.

97. Life Spine spent hundreds of thousands of dollars to attempt to develop and bring the plate to market but encountered a number of setbacks. Life Spine knew that it was unlikely that the product would be approved by the FDA but continued the project to retain Dr. B's business.

98. In 2016, Greiber participated in discussions with Dr. B during which Life Spine's continued funding of the plate project and the surgeon's recent decreased usage of Life Spine Products were discussed. In sum and substance, Greiber asked Dr. B to commit to increasing his usage of Life Spine Products if he wanted Life Spine to continue to fund his project. Greiber linked future project funding to Dr. B's agreement to increase his product usage to prior levels. Greiber asked Dr. B for the "commitment we can expect from your end," and also requested Dr. B to "see your way back to instead of just having us in the rotation, making us first and foremost" among the implants Dr. B used in his surgeries. Life Spine executives explained to Dr. B and his representative that they had already spent more than $300,000 developing Dr. B's plate and expected Dr. B to "do cases to be able to fund this program" going forward. Dr. B responded that he was "willing to go back and use [Life Spine] in good faith" in exchange for Life Spine's commitment to push the plate through to approval.

99. Butler also personally told Dr. B that he needed to use more Life Spine Products in order for Life Spine to continue to cover costs associated with the development of the plate.

100. Dr. B used Life Spine Products when performing spinal surgeries on a significant number of Medicare and Medicaid patients at various hospitals, including Castle Rock Adventist Hospital and Sky Ridge Surgical Center. Medicare Part A, Medicare Part B, and Medicaid claims relating to these surgeries were submitted and paid. Those claims were false because they were tainted by illegal kickbacks and thus were ineligible for reimbursement.

C. A Texas-based Surgeon

101. Life Spine entered into two IP Agreements with Texas-based surgeon Dr. C, one in December 2016, and the other in December 2017. Each agreement included a $120,000 acquisition fee as well as 20,000 warrants for shares in Life Spine.

102. Dr. C did not use Life Spine Products until late 2016, shortly before he executed the first IP Agreement. Dr. C was responsible for more than $1.7 million in product sales through the end of 2018.

103. Life Spine employees closely monitored Dr. C's usage of Life Spine Products. In late 2017, Life Spine noticed that Dr. C's numbers had declined. This prompted a meeting between Dr. C and a senior Life Spine manager.

104. According to a text from that manager summarizing the meeting, Dr. C was provided with a check from Life Spine — presumably related to the IP Agreement — which was "much appreciated" by the surgeon, and then was "challenged on his usage." The manager reported that they "spoke at length about how to get his usage to $100k per month," and Dr. C. responded "I have to do better for you guys." As the manager summed up, "[l]ong story short, he seems on board and wanting to fulfill his commitment."

105. Approximately two weeks later, the same manager conveyed Dr. C's weekly sales data to the Vice President of Marketing and Business Development and stated: "I think he is back in the saddle! . . . Roughly $42k from [Dr. C] this week alone. I've sent a thank you note, you might want to hit him real quick as well."

106. In February 2019, Dr. C and Life Spine were in the process of finalizing a new IP Agreement related to a "cervical facet implant system."

107. Dr. C used Life Spine Products when performing spinal surgeries on a significant number of Medicare patients, including at Arise Austin Medical Center and The Hospital at

Westlake Medical Center. Medicare Part A and Medicare Part B claims relating to these surgeries were submitted and paid. Those claims were false because they were tainted by illegal kickbacks and thus were ineligible for reimbursement.

D. An Illinois-based Surgeon

108. Beginning in 2013, Life Spine retained Illinois-based surgeon Dr. D to provide consulting services. Life Spine paid Dr. D more than $60,000 in consulting fees and royalties during the Relevant Period.

109. Among other things, Life Spine paid Dr. D to train Life Spine employees and interns by allowing them to observe her perform surgeries.

110. Life Spine tracked Dr. D's usage of its products and pressured her to increase her usage based on her status as a Paid Surgeon.

111. For example, on August 23, 2016, after Butler had pressured Dr. D for more sales during a dinner, Dr. D emailed Butler and her distributor "a few thoughts about my relationship with Lifespine that still bothered me . . . after our conversation." Dr. D explained, "I do understand how development works and how usage provides the funds and sometimes the test bed for new product development." Dr. D continued, "[t]o suggest that I have not been utilizing LifeSpine is erroneous and honestly insulting. . . . I understand that as a company you'd like to earn all my business as well as utilize my experience in the development of your systems but as you said this stream goes both ways. As of late there have been very few consulting hours or labs. My occasional usage of other companies is not based on this as retribution. The occasional usage is to first, eliminate the perception of a 'bought' surgeon and second, to gain understanding of ideas I may be able to bring to LifeSpine. It is not as a divergence from my commitment to work with LifeSpine."

112. Dr. D generated more than $2.7 million in sales revenue for Life Spine during the Relevant Period. She rarely used Life Spine Products prior to being retained as a consultant.

113. Dr. D used Life Spine Products when performing spinal surgeries on a significant number of Medicare and Medicaid patients at various hospitals, including Morris Hospital & Healthcare Centers, Amita Health Saint Joseph Hospital Chicago, and Amita Health Adventist Medical Center Bolingbrook. Medicare Part A, Medicare Part B, and Medicaid claims relating to these surgeries were submitted and paid. Those claims were false because they were tainted by illegal kickbacks and thus were ineligible for reimbursement.

VII. Defendants Were Aware of AKS Risks but Failed to Implement an Effective Compliance Program.

114. Life Spine executives, including Butler and Greiber, were well aware that paying surgeons who were also users of Life Spine Products presented legal risks under the AKS.

115. Life Spine had a compliance policy entitled "Consulting Surgeon Relationships and Corporate Compliance" that prohibited entering consulting agreements to generate business. However, this policy was not enforced and was repeatedly and blatantly violated.

116. During the vast majority of the Relevant Period, Life Spine failed to develop and implement an effective compliance program. Life Spine had a decentralized and ineffective process to vet consultant candidates and to review and approve agreements to ensure that they did not present any AKS concerns. In addition, Life Spine failed to adequately review "work reports" that were supposed to document the consulting services that Paid Surgeons rendered prior to disbursing payments to surgeons.

117. Life Spine did not have a compliance department until mid-2018, instead designating a single employee, who had many other duties, to handle compliance issues at the company. Greiber served as the compliance point person while he was Vice President of

Business Development and Professional Relations even though he had no formal AKS training or expertise prior to assuming that role. Greiber failed to develop and implement an effective compliance program to ensure that the company did not use Med Ed Agreements, PD Agreements, and IP Agreements as a means to funnel payments to surgeons to induce them to use Life Spine Products.

VIII. Defendants Caused Hundreds of False Claims to Be Submitted and Paid for by Medicare and Medicaid.

118. Life Spine, with the knowledge, involvement, and participation of Butler and Greiber, knowingly and willfully paid surgeons kickbacks in the form of consulting fees, royalties, and IP acquisition fees to induce them to use Life Spine's Products when performing spinal surgeries. Many of these surgeries were performed on Medicare and Medicaid patients.

119. Defendants are liable for damages based on the payment of claims submitted to Medicare and Medicaid for medical services and procedures involving Life Spine Products that were tainted by illegal kickbacks.

120. The certifications and attestations signed by Paid Surgeons and the hospitals where they operated certified compliance with the AKS. Kickbacks that were paid to doctors as alleged herein rendered those certifications and attestations false. Those false statements were material to the false claims submitted for services provided by surgeons who took the kickbacks and to the false claims submitted by hospitals for the inpatient services rendered, including the cost of the implants and other Life Spine Products used in the surgeries. All claims resulting from illegal kickbacks are considered false claims for purposes of the FCA because, as recognized by Congress, paying kickbacks to persons who can influence health care decisions can put patient safety at risk, and result in higher healthcare costs, including through the provision of goods or services that are medically unnecessary. *See supra* ¶¶ 14-17.

121. Defendants intended that these payments to surgeons would induce them to use Life Spine Products, and it was reasonably foreseeable that some of those products would be used in surgeries performed on Medicare and Medicaid patients and that claims related to those surgeries would be submitted to Medicare or Medicaid. In fact, hundreds of claims that were tainted by kickbacks were submitted to and paid for by Medicare or Medicaid.

COUNT I (Against All Defendants)

Violations of the FCA: Causing False Claims To Be Presented for Payment (31 U.S.C. § 3729(a)(1)(A))

122. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

123. The United States seeks relief against Defendants under 31 U.S.C. § 3729(a)(1)(A).

124. As a result of Defendants' knowing and willful payment of remuneration to induce surgeons to use Life Spine Products in violation of the AKS, 42 U.S.C. § 1320a-7b(b)(2), false and fraudulent claims for payment were made to Medicare and Medicaid. Accordingly, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

125. By reason of these false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

COUNT II (Against All Defendants)

Violations of the FCA: Use of False Statements
(31 U.S.C. § 3729(a)(1)(B))

126. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

127. The United States seeks relief against Defendants under 31 U.S.C. § 3729(a)(1)(B).

128. As a result of Defendants' knowing and willful payment of remuneration to induce surgeons to use Life Spine Products in violation of the AKS, 42 U.S.C. § 1320a-7b(b)(2), Defendants knowingly caused surgeons and hospitals to make or use false records or statements that were material to false or fraudulent claims for payment submitted to Medicare and Medicaid.

129. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

COUNT III (Against Life Spine)

Unjust Enrichment

130. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

131. Through the acts set forth above, Life Spine has received payments in the form of product sales to which it was not entitled and therefore has been unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, Life Spine should not retain those payments, the amount of which is to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests judgment to be entered in its favor as follows:

a. On Counts I and II, a judgment against Defendants for treble damages and civil penalties to the maximum amount allowed by law.

b. On Count III (unjust enrichment), a judgment against Life Spine for damages to the extent allowed by law.

c. Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

Dated: New York, New York
July 22, 2019

Respectfully submitted,

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